

**REMARKS**

Applicants thank the Examiner for consideration of the subject patent application. In the office action mailed July 14, 2004, Claims 1-145 were pending, and made subject to restriction requirement and further to an election of species requirement under 35 U.S.C. § 121. Particularly, the Examiner indicated the existence of two patentably distinct inventions in the claims as follows:

1) Group I constituting Claims 1-133, drawn to a pharmaceutical composition, classified in class 424, subclasses 489, 464, and 451; and 2) Group II constituting Claims 134-145, drawn to methods, classified in class 424, subclass 464, 489, and 451. The Examiner further indicated the existence of five patentably distinct species within Group I and three species within Group II.

as follows:

**Group I**

1. A pharmaceutical formulation wherein an active agent has a first fraction suspended in a vehicle and a second fraction solubilized in a vehicle;
2. A pharmaceutical formulation wherein a first active agent has a first fraction suspended in a vehicle and a second fraction solubilized in a vehicle and additionally a second active agent that is solubilized or suspended in the vehicle;
3. A pharmaceutical formulation wherein an active agent has a first fraction suspended in a vehicle and a second fraction solubilized in a vehicle, which is substantially free of added water;
4. A pharmaceutical formulation comprising an active agent that has a first fraction suspended in a vehicle and a second fraction solubilized in a vehicle, wherein the

process of preparing the composition involves the step of coating the interfacial agent on the particles;

5. A pharmaceutical formulation comprising an active agent that has a first fraction suspended in a vehicle and a second fraction solubilized in a vehicle, wherein the composition further comprises a means for segregating the first and second fractions.

Group II

1. A method for reducing the effect of food on absorption and bioavailability of orally administered agent to a patient;
2. A method for increasing the onset of therapeutic effect of an active agent and reducing time to apparent elimination; and
3. A method for reducing the interpatient variability with respect to absorption and bioavailability.

Finally, the Examiner indicated that Claim 1 was generic with respect to Group I, and that Claim 134 was generic with respect to Group II.

A review of Claims 1-133 in Group I reveals that each and every claim of this group reads on a formulation wherein an active agent has a first fraction suspended in a vehicle and a second fraction solubilized in a vehicle as indicated by Species 1. Therefore, pursuant to the present election of Group I, Species 1, Claims 1-133 remain pending for consideration in the present application, and Claim 134-145 are withdrawn.

### CONCLUSION

If any impediment remains to examination after consideration of the above-recited remarks, which could be removed during a telephone interview, the Examiner is invited to telephone Mr. David Osborne of this office, or in his absence, the undersigned attorney at (801) 566-6633 so that such issues may be resolved as expeditiously as possible.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 20-0100.

DATED this 13<sup>th</sup> day of September, 2004.

Respectfully submitted,

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